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09/438,872 11/12/99 COCHRUM

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EXAMINER

HM22/0201

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SAUCIER, S

ART UNIT

PAPER NUMBER

1651

8

DATE MAILED:

02/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

BEST AVAILABLE COPY

Office Action Summary

Application No.
09/438,872

Applicant(s)

Cochrum et al.

Examiner
Sandra Saucier

Group Art Unit
1651



☒ Responsive to communication(s) filed on Dec 22, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-44 is/are pending in the application.

Of the above, claim(s) 14-40 and 42-44 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-13 and 41 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Please note that the serial number of the instant application is 09/438872 not 09/290846. Applicants used the wrong serial number on their reply to the restriction requirement mailed 11/28/00. Use of the wrong serial number on responses could lead to inadvertent abandonment.

Claims 1-44 are pending. Claims 1-13 and 41 are considered on the merits. Claims 14-40, 42-44 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 14-40, 42-44 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 7.

Priority

Please clarify how the instant application is related to 60/108185 and 09/290846. For example, is this application a continuation in part of 09/290846? Is 09/290846 the non-provisional filing of the specification of 60/108185 or does it have added matter?

Please correct the first paragraph to accurately reflect the relationship between these applications.

Specification

The disclosure is objected to because of the following informalities:

The attempt to incorporate subject matter into this application by reference to an article by Mann on page 3 and on page 11, line 12 by incorporation of "references" is improper because only US Patent documents may be incorporated by reference.

On page 19, details regarding bifunctional substance used to manufacture the "novel" hemostatic polymer are said to be disclosed in Swedish Patent 865265. This appears to be critical to the enablement of the invention and should be properly incorporated, see below.

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by

reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

On page 21, second paragraph, "alcohol's" should not have an apostrophe.

On page 21, third paragraph, almost all of the chemical names are misspelled.

Appropriate correction is required.

Claim Rejections – 35 USC § 112
INDEFINITE

Claims 1-14 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 it is not clear if the "matrix" and the "zone" are the same constructs. Please explain how the "zone" relates to the "matrix". Please bear in mind that this is an article which is being described. A claim to an article should describe how the pieces of the article are related to one another.

Claim 2 does not specify how the substrate is related to the matrix. The claim is directed to an article, but the parts of the article are not defined with respect to their relationship to one another.

Claim 2 recites "containing organic hydroxyl groups". However, a hydroxyl group does not contain organic material. It does not even contain a carbon atom. Thus, this phrase is vague and is not interpretable.

Claim 2 states that an uncharged "substance" and a bifunctional "substance" are reacted to form the hemostatic polymer.

Is a "substance" the same or different from a compound? A substance is not a term of art when referring to chemical compounds or to chemical reactions.

Claim 2 also states that the one of the reactants is "bifunctional". Usually this means that two reactive groups are in a single molecule. The claim goes on to further state "and a bifunctional substance containing at least one of a halogen atom and an epoxy group". This is interpreted to mean that the compound needs to have only one halogen atom or only one epoxy group to satisfy the claim limitations. How can an alkane with only one halogen atom be considered to be "bifunctional". Please explain.

Claims 3, 4 and 9 have no precedent for the recitation of "the substance".

Claim 5 has no precedent for the recitation of "the carbohydrate".

Claim 8 has no precedent for the recitation of "the polyol".

In claim 9, "epichlorohydrin" is misspelled.

Claim 10 has no precedent for the recitation of "the epoxy group".

Claim 11 has no precedent for the recitation of "the hemostatic polymer composition".

Claim 12 does not specify how the pharmaceutical agent is related to the wound dressing. The wound dressing is an article with structure which is not clearly defined.

SCOPE

Claims 1-13 and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while it might be enabling for the use of dextran cross linked with epichlorohydrin and with an exclusion limit of 300,000, does not reasonably provide enablement for other polymers. The polymers are described in the specification as being novel. However, it is assumed that Swedish Patent 865265 describes the making of dextran cross-linked with epichlorohydrin and with an exclusion limit of 300,000 and that this specific material is not novel, contrary to multiple statements found throughout the specification, and, if so, the process will be properly incorporated into the specification. If this is not so, the entire specification may be held to unenabled because it does not teach how to make the novel polymers required to practice the claimed invention.

The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

NATURE OF THE INVENTION

The invention is directed to a wound dressing which comprises an hemostatic agent.

BREADTH OF THE CLAIMS

The claims encompass the use of any and all hemostatic agents which are polymers which are the product of a reaction of an uncharged substance containing organic hydroxyl groups and a bi-functional substance containing at least a halogen atom or/and a hydroxy group.

AMOUNT OF GUIDANCE AND WORKING EXAMPLES

No teaching of how to make any polymer is present in the case. It is assumed that the improperly incorporated Swedish patent discloses a polymer made of dextran cross-linked with epichlorohydrin with an exclusion of 300,000, and that applicants will properly incorporate the material.

STATE OF THE PRIOR ART AND UNPREDICTABILITY

Since the polymers are repeatedly described as being novel, the prior art cannot teach how to make them, nor is there any reference to a published description of the process of making such polymers.

Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and limited number of working examples in the specification, the nature of the invention, the state of the prior art, breadth of the claims and the unpredictability of the art.

As set forth in *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA) 1970: [Section 112] requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.

In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of the enablement varies inversely with the degree of unpredictability of the factors involved. *Ex parte Humphreys*, 24 USPQ2d, 1260.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States, (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4, 6, 7, 9, 12 and 13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 4793336 [A].

The claims are directed to a dry, sterile, stable wound covering comprising a polymer made by reacting an uncharged organic compound with hydroxyl groups (dextran) with a bifunctional compound (epichlorohydrin) and a matrix.

US 479336 disclose a wound covering comprising a dextran polymer crosslinked with epichlorohydrin and having a matrix of cellophane or woven textile (col. 3, l. 66). The dextran polymer has been immersed in 15% isopropanol in propylene glycol which would displace the water adsorbed in the polymer and sterilize the composition. Therefore, the polymer composition is dry because it has little or no water remaining in the composition. The wound covering may additionally comprise other medicaments such as antibacterial drugs (col. 4, l. 58).

Claims 1-4, 6, 7, 9, 10, 12 and 13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by GB 1454055 [N].

GB 1454055 discloses a wound dressing comprising a dextran-epichlorohydrin polymer and a matrix which may be paper, cotton fabric, inert plastics, etc. (page 6). Disinfectants may be added to the carrier (page 6, l. 36). Sterilization may be by gamma irradiation (p. 6, l. 130).

It cannot be ascertained from the description of the specification whether the form of the polymer is the same as that of the references; however, in the

absence of evidence, it is assumed to be the same in order to expedite prosecution.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1454055 [N] or US 4793336 [A] as applied to claims 1-4, 6, 7, 9, 10, 12 and 13 above, and further in view of Larson [R] or Eloy *et al.* [S] and US 5196190 [B].

The claim is directed to a wound dressing comprising a matrix, a hemostatic polymer such as cross-linked dextran and collagen or thrombin or fibrinogen.

Collagen, fibrinogen or thrombin are known hemostatic agents as describe by Larson [R] or Eloy *et al.* [S]

US 5196190 teaches that cross-linked dextran has hemostatic properties (col. 10, l. 50).

The addition of thrombin or fibrinogen or collagen to the wound dressing of US 4793336 or GB 1454055 would have been obvious when the reference was taken with Larson or Eloy *et al.* and US 5196190 because cross-linked dextran, thrombin, fibrinogen and collagen are known hemostatic agents and have been used in the past as such.

It is well known that it is prima facie obvious to combine two or more

ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

The references are relied upon as explained below.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1454055 [N] or US 4703336 [A] as applied to claims 1-4, 6, 7, 9, 10, 12 and 13 above, and further in view of US 4549653 [C].

The claims are further directed to the composition of claim 1 which is a dry, sterile, stable wound covering comprising a matrix containing a polymer made by reacting an uncharged organic compound with hydroxyl groups (dextran) with a bifunctional compound (epichlorohydrin) further incorporating a flexible substrate sheet and a protective layer enclosing it.

US 4549653 discloses a strip used as a wound covering comprising a flexible substrate sheet carrying a dry sterile wound dressing and a protective covering.

The enclosure of the flexible, sterile wound covering of GB 1454055 or US 4703336 in the enclosure of US 4549653 would have been obvious because it is well known in the art to form enclosures for wound dressings to maintain cleanliness.

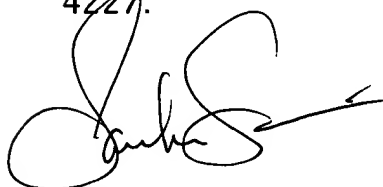
One of skill in the art would have been motivated at the time of invention to make these substitutions or additions in order to obtain the resulting composition or article as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743.

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Art Unit: 1651

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Service Desk at (703) 308-0196. The number of the Fax Center for the faxing of papers is (703) 308-4227.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a long horizontal stroke extending to the right.

Sandra Saucier
Primary Examiner
Art Unit 1651
January 30, 2001